

Application No. 10/574,393
Amendment dated April 22, 2009
First Preliminary Amendment

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Docket No.: 65138(53253)

AMENDMENTS TO THE CLAIMS

This listing of claims will replace all prior versions and listings of claims in the application:

1. (previously presented) A method of altering a specific immune response to an antigen in an individual sensitized to the antigen comprising:
 - i). administering to the individual an effective amount of the antigen in immunotherapeutic form, wherein said immune response is down regulated; and
 - ii). subsequently administering to the individual an effective amount of an immunomodifying agent comprising the antigen in immunogenic form.
2. (previously presented) A method according to claim 1, wherein the immunomodifying agent further comprises either a TH1 or TH2 adjuvant, wherein the adjuvant normally induces the type of TH-response which is the target of the immunotherapy.
3. (amended) A method according to claim 1 ~~or claim 2~~, wherein the immunotherapy is targeted at the specific immune response.
4. (amended) A method according to ~~any one of~~ claims 1 to 5, wherein the effective amount in step i) is one or more doses of said antigen in immunotherapeutic form.
5. (amended) A method according to ~~any one of~~ claims 1 to 5, wherein said antigen in immunotherapeutic form further comprises agents designed to modulate the specific immune responses.
6. (amended) A method according to ~~any one of~~ claims 1 to 5, wherein the alteration to the specific immune response is attenuation of the TH-response component, which is associated with expression of the disease being treated.
7. (amended) A method according to ~~any one of~~ claims 1 to 5, wherein the alteration to the specific immune response is conversion of the TH1 component of the response to a TH2 component or conversion of the TH2 component to a TH1 component.
8. (amended) A method according to ~~any one of~~ claims 1 to 5, wherein the alteration to the specific immune response is reversing the ratio between the TH1 and TH2 components of the response.

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9. (previously presented) A method according to claim 8, wherein the immune response in an untreated individual comprised high level production of TH1 cytokines and low level production of TH2 cytokines is reversed following treatment.
10. (previously presented) A method according to claim 8, wherein the immune response in an untreated individual comprised high level production of TH2 cytokines and low level production of TH1 cytokines is reversed following treatment.
11. (previously presented) A method of treating a TH1-associated disease comprising:
i). administering to an individual in need thereof an effective amount of an antigen in immunotherapeutic form; and
ii). subsequently administering to the individual an effective amount of an immunomodifying agent comprising said antigen in immunogenic form, wherein the antigen specific TH1 response in the individual is reduced relative to the specific TH1 response before administration of said immunomodifying agent.
12. (previously presented) A method according to claim 11, wherein the immunomodifying agent further comprises a TH1 adjuvant.
13. (previously presented) A method of treating a TH2-associated disease comprising:
i). administering to an individual in need thereof an effective amount of an antigen in immunotherapeutic form; and
ii). subsequently administering to the individual an effective amount of an immunomodifying agent comprising said antigen in immunogenic form, wherein the antigen specific TH2 response in the individual is reduced relative to the specific TH2 response before administration of said immunomodifying agent.
14. (previously presented) A method according to claim 13, wherein the immunomodifying agent further comprises a TH2 adjuvant.
15. (previously presented) A method of treating a disease associated with a mixed TH1 and TH2 immune response comprising:
i). administering to an individual in need thereof an effective amount of an antigen in immunotherapeutic form; and
ii). subsequently administering to the individual an effective amount of an immunomodifying agent comprising said antigen in immunogenic form which boosts both TH1

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and TH2 immunity, wherein ensuing specific TH1 and TH2 responses in the individual are reduced relative to the specific TH1 and TH2 responses before administration of said immunomodifying agent.

16. (previously presented) A method according to claim 15, wherein the immunotherapeutic form in step i) is sublingual administration of antigen.
17. (amended) A method according to claim 15 ~~or claim 16~~, wherein the immunomodifying agent in step ii) is administered parenterally.
18. (amended) A method according to ~~any one of claims 15 to 18~~, wherein the immunomodifying agent further comprises either an adjuvant which boosts both TH1 and TH2 immunity or a mixture of TH1 and TH2 adjuvants, wherein ensuing specific TH1 and TH2 responses in the individual are reduced relative to the specific TH1 and TH2 responses before administration of said immunomodifying agent.
19. (previously presented) A method according to claim 1, wherein the immunotherapy is administration to an individual in need thereof an effective amount of one or more antigen(s) in immunotherapeutic form, wherein the antigens are associated with expression of pathogenic TH2 immunity.
20. (amended) A method according to claim 21, wherein the individual suffers from a TH1-associated disease and the antigen in immunotherapeutic form is predominately a TH1-specific antigen.
21. (previously presented) A method of treating a disease comprising:
i). administering to an individual in need thereof an effective amount of an antigen in immunotherapeutic form, wherein the immune response to said disease is down regulated; and
ii). subsequently administering to the individual an effective amount of an immunomodifying agent comprising said antigen in immunomodifying form.
22. (amended) A method according to claim ~~21~~22, wherein the immunomodifying agent further comprises either a TH1 or TH2 adjuvant, wherein the adjuvant normally induces the type of TH-response which is the target of the immunotherapeutic form of the antigen.

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23. (amended) A method according to claim 212, wherein the disease is a TH1-associated disease selected from the group consisting of rheumatoid arthritis, multiple sclerosis, thyroiditis, Crohn's disease, systemic lupus erythematosus, experimental autoimmune uveoretinitis, experimental autoimmune encephalitis, insulin dependent diabetes mellitus, contact dermatitis and chronic inflammatory disorders.
24. (amended) A method according to claim 212, wherein the disease is a TH2-associated disease selected from the group consisting of allergic atopic disorders, allergic asthma, atopic dermatitis, hyper-IgE syndrome, Omenn's syndrome, and allergic rhinitis.
25. (previously presented) A method according to claim 2, wherein the TH2 adjuvant is selected from the group consisting of alum, pertussis toxin, lacto fucopentaose III, and phosphopolymer or combinations thereof.
26. (previously presented) A method according to claim 2, wherein the TH1 adjuvant is selected from the group consisting of complete Freund's adjuvant, monophosphoryl lipid A, 3-de-O-acylated monophosphoryl lipid A (3D-MPL), aluminum salt, CpG-containing oligonucleotides, immunostimulatory DNA sequences, saponin, Montanide ISA 720, SAF, ISCOMS, MF-59, SBAS-3, SBAS-4, Detox, RC-529, aminoalkyl glucosaminide 4-phosphate, and LbeIF4A.
27. (amended) A method according to ~~any one of~~ claims 1 to 27, wherein the individual is a mammalian animal.
28. (amended) A method according to claim 278, wherein the mammalian animal is a dog, a cat, a livestock animal, a primate or a horse.
29. (amended) A method according to claim 278, wherein the mammalian animal is a human.
30. (previously presented) A kit used for altering TH1 or TH2 response phenotype in an individual in need thereof comprising:
- i). one or more TH1 antigen(s); or
 - ii). one or more TH1 or TH2 adjuvant(s); or
 - iii). combinations thereof; and
 - iv) instructions for use.

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31. (previously presented) A method of immunotherapy comprising:
i). administration to an individual in need thereof a plurality of antigen shots;
ii). administration to said individual less than five individual shots of said antigen combined with one or more TH1 and/or TH2 adjuvant(s).
32. (amended) A method according to claim 31, wherein the individual shots of said antigen combined with TH1 and/or TH2 adjuvant is less than three.
33. (amended) A method according to claim 31, wherein the individual shots of said antigen combined with TH1 and/or TH2 adjuvant is one.
34. — 49. (cancelled)
50. (previously presented) An immunomodifying agent comprising at least one antigen in immunogenic form and at least one adjuvant, wherein the adjuvant normally induces the type of TH-response associated with the disease caused by said antigen.
51. (new) A method according to claim 13, wherein the immunogenic form of the antigen will be administered subcutaneously and the immunotherapeutic form is administered sublingually.